PATENT
Attorney Docket No. 04012.0385-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)
Lukas-Laskey et al.	) Group Art Unit: 1614
Application No.: 10/721,020	) Examiner: K. Weddington
Filed: November 25, 2003	)
For: METHOD OF TREATMENT FOR DECREASING MORTALITY RESULTING FROM CONGESTIVE HEART FAILURE	) Confirmation No.: 3994

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Examiner the documents on the attached listing. This Information Disclosure Statement is being filed before the mailing date of a first Office Action after the filing of a Request for Continued Examination in the above-referenced application.

Copies of the listed non-patent literature documents are attached, all of which relate to pediatric studies conducted with carvedilol. Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

For each of the two "Clinical Study Reports" included herewith, appendixes containing individual patient-related information and reportings have not been included

in order to protect any confidential patient-related information, which is also understood to be, at most, cumulative with the substantive material contained in the Reports.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserves the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: October 11, 2006

By: _____
Mark J. Feldstein
Reg. No. 46,693

IDS Form PTO/SB/08: Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	1

Complete if Known	
Application Number	10/721,020
Filing Date	November 25, 2003
First Named Inventor	Lukas-Laskey et al.
Art Unit	1614
Examiner Name	K. Weddington
Attorney Docket Number	04012.0385-00000

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-			
		US-			
		US-			
		US-			
		US-			
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Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation[6]

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation[6]
		CLELAND et al., "Clinical trials update from the American College of Cardiology: darbepoetin alfa, ASTEROID, UNIVERSE, paediatric carvedilol, UNLOAD and ICELAND," European Journal of Heart Failure, 8, pp. 326-329, 2006.	
		SHADDY et al., "The pediatric randomized carvedilol trial in children with chronic heart failure: Rationale and design," American Heart Journal, vol. 144, no. 3, pp. 383-389, September 2002.	
		Summary Report, Study No.: SK&F-105517/321, "A Multicenter, placebo-controlled, 8-month study of the effect of twice daily carvedilol in children with congestive heart failure due to systemic ventricular systolic dysfunction," pp. 1-9, July 2006.	
		Clinical Study Report, Study No.: SK&F-105517/321, "A Multicenter, placebo-controlled, 8-month study of the effect of twice daily carvedilol in children with congestive heart failure due to systemic ventricular systolic dysfunction," abstract and cover pp. 1-4 and Clinical Study Report pp. 1-238, 266, 342-360, July 17, 2006	
		Summary Report, Study No.: SK&F-105517/396, "A Multicenter Open-label Extension Study to Evaluate the Safety of Twice Daily Oral Carvedilol in Pediatric Subjects with Chronic Heart Failure," abstract and cover pages pp. 1-4.	
		Clinical Study Report, Study No.: SK&F-105517/396, "A Multicenter Open-label Extension Study to Evaluate the Safety of Twice Daily Oral Carvedilol in Pediatric Subjects with Chronic Heart Failure," abstract and cover pages pp. 1-4 and Clinical Study Report pp. 1-135., August 2006.	

Examiner Signature		Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.